



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,622	03/18/2004	John McCafferty	05569.0004.DVUS11	6206

7590 10/02/2007
HOWREY SIMON ARNOLD & WHITE, LLP
Attention: Box No. 34
1299 Pennsylvania Avenue, N.W.
Washington, DC 20004-2402

EXAMINER	
STEELE, AMBER D	

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
10/02/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/803,622

Applicant(s)

MCCAFFERTY ET AL.

Examiner

Amber D. Steele

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 13-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on March 18, 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/726,219.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 8, 2007 has been entered.

Status of the Claims

2. The amendment to the claims received on August 8, 2007 amended claim 9.

Claims 1-17 are currently pending.

Claims 9 and 13-17 are currently under consideration.

3. Please note: claims 1-8 which are drawn to an invention nonelected without traverse in the response received on April 27, 2006 were not cancelled in response to the Final Office action mailed on April 10, 2007 (please refer to 37 CFR 1.144 and MPEP § 821.01). In addition, claims 10-12 have improper status identifiers (i.e. original instead of withdrawn).

Election/Restrictions

4. Claims 1-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on April 27, 2006.

Art Unit: 1639

5. Claims 10-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 27, 2006.

Priority

6. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) of United Kingdom application 9015198.6 7/10/1990; United Kingdom application 9022845.3 10/19/1990; United Kingdom application 9024503.6 11/12/1990; United Kingdom application 9104744.9 3/6/1991; United Kingdom application 9110549.4 5/15/1991. The certified copies have been filed in parent Application No. 09/726,219, filed on November 28, 2000.

7. The present application claims status as a DIV of 09/726,219 11/28/2000 PAT 6,806,079 which is a CON of 08/484,893 06/07/1995 PAT 6,172,197 which is a CON of 07/971,857 01/08/1993 PAT 5,969,108 which is a National Stage application filed under 35 U.S.C. § 371 of PCT/GB91/01134 07/10/1991.

Withdrawn Rejection

8. The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Ladner et al. WO 90/02809 published March 22, 1990 and Ladner et al. WO 88/06630 published September 7, 1988 is withdrawn in view of the claims amendment received on August 8, 2008.

Maintained Rejections

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

10. Claims 9 and 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Dower et al. U.S. Patent 5,427,908 filed May 1, 1990.

For present claim 9, Dower et al. teach methods of producing filamentous bacteriophage surface expressing binding domains of antibody fragments including VH that are encoded by nucleic acid sequences and screening the libraries of filamentous bacteriophage including fd, fl, and M13 expressing the VH against various antigens, antigenetic determinants, or haptens in order to select a specific binding domain (please refer to the entire specification particularly the abstract; columns 1-12; Example I). Dower et al. specifically teach phage display of VH only (please refer to column 3, lines 28-42).

For present claim 13, Dower et al. teach isolating the nucleic acid encoding the antibody fragments from spleen (i.e. peripheral lymphoid tissue, peripheral blood lymphocytes, B-lymphocytes; please refer to column 4 and Example I).

For present claim 14, Dower et al. teach bacteriophage vectors (i.e. phagemid; please refer to the entire specification particularly the abstract; column 1, lines 60-67; column 2, lines 15-43; Example I).

For present claim 15, Dower et al. teach that the nonbound antibodies are washed away and the bound phage can be eluted from the antigen or hapten (please refer to column 10, lines 62-67; column 11, column 12, lines 1-23).

Art Unit: 1639

For present claim 16, Dower et al. teach that the previously antigen or hapten bound phage are recovered (please refer to column 11, lines 60-67; column 12, lines 1-31).

For present claim 17, Dower et al. teach recloning DNA from the eluted and recovered previously antigen or hapten bound phage particles via expression in a suitable eukaryotic or prokaryotic expression vector for production of large amounts of the binding domain protein (please refer to column 12, lines 32-41).

Therefore, the present invention is anticipated by the teachings of Dower et al.

Arguments and Response

11. Applicants' arguments directed to the rejection under 35 USC 102 (e) as being anticipated by Dower et al. for claims 9 and 13-17 were considered but are not persuasive for the following reasons.

Applicants contend that Dower et al. only claims screening Fab; the only example provided by Dower et al. teaches screening Fab; and Dower et al. teach multichain proteins including Fab, lytic bacteriophage, and separate cloning vectors for VL and VH but only for combining the VH and VL later.

Applicants' arguments are not convincing since the teachings of Dower et al. anticipate the method for producing a phage displaying VH. Dower et al. teach various embodiments however this does not preclude the teachings of Dower et al. regarding the use of filamentous phage as the preferred phage (please refer to the entire specification particularly column 2, lines 14-21) and displaying VH alone (please refer to the entire specification particularly column 3, lines 28-42; column 4, lines 56-67; column 8, lines 44-57). Specifically, Dower et al. teach the antibody may be single-chain, two-chain, or a portion thereof including only the variable

Art Unit: 1639

antigen-binding regions of heavy (VH) and/or light (VL) chains; phage can be utilized for expression of antibody sequences including VH; phage display libraries expressing VH only can be produced (please refer to columns 3-4, 8).

MPEP § 2123 reads: "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Upsher-Smith Labs. v. Pamlab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005), *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998).

New Rejection

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1639

13. Claims 9 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladner et al. WO 90/02809 published March 22, 1990 and Sastry et al. PNAS 86: 5728-5732, 1989 (provided by applicants in the IDS).

For present claims 9 and 14-17, Ladner et al. teach methods of surface displaying binding domains on filamentous bacteriophage particles wherein the binding domains (i.e. scFv comprising VH and VL) are encoded by nucleic acid sequences and then screened via binding to targets (please refer to abstract; pages 8-14; pages 17-18; pages 42-48). In addition, Ladner et al. teach bacteriophage vectors (i.e. phagemids), separation of unbound phage, separation of phage from antigen, recovery of phage, and producing additional phage display libraries (please refer to the entire specification particularly pages 8, 11-15, 18, 42-45).

However, while Ladner et al. (WO 90/02809) discuss the expression of scFv on the surface of filamentous phage, the expression of VH only is not taught.

For present claims 9 and 13, Sastry et al. teach methods of displaying VH utilizing lambda phage wherein the VH are obtained from lymphocytes (please refer to the entire reference particularly the Materials and Methods section).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to alter the methods of screening filamentous phage displaying proteins of Ladner et al. with the VH of Sastry et al.

One having ordinary skill in the art would have been motivated to do this because Sastry et al. teach that the heavy chains are responsible for the majority of antigen binding affinity of antibodies (please refer to the introduction section, page 5728, right column).

Art Unit: 1639

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the methods of screening filamentous phage displaying proteins of Ladner et al. with the VH of Sastry et al. because Ladner et al. (WO 90/02809) teach screening methods of phage-displayed proteins that are between 46 and 164 residues in length (e.g. VH approximately 100-120 residues in length; please refer to page 50, lines 29-35).

Therefore, the modification of the methods of screening filamentous phage displaying proteins of Ladner et al. (WO 90/02809) with the VH of Sastry et al. render the instant claim *prima facie* obvious.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1639

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS

September 24, 2007

A handwritten signature in black ink, appearing to read 'Mark L. Shibuya', written in a cursive style.

MARK L. SHIBUYA
PRIMARY EXAMINER